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10/593,653	09/21/2006	Vlasios Andronis	PB60811	2987
20462 7590 06/24/2009 SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939				
EXAMINER PIHONAK, SARAH				
ART UNIT		PAPER NUMBER		
1617				
NOTIFICATION DATE		DELIVERY MODE		
06/24/2009		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US\_cipkop@gsk.com

### Office Action Summary

**Application No.**

10/593,653

**Applicant(s)**

ANDRONIS ET AL.

**Examiner**

SARAH PIHONAK

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This application is a 371 (national stage application) of PCT/US05/10350, filed on 3/28/2005.

#### ***Priority***

This application, which was filed on 9/21/2006, also claims priority from Provisional application No. 60/557571, filed on 3/30/2004. The provisional application provides support to the instant claims; therefore, the priority date and effective filing date given to the instant claims is 3/30/2004.

#### ***Response to Arguments***

1. In the response filed on 4/13/2009, the Applicants requested clarification regarding form PTOL-326, section titled "Priority under 35 U.S.C. § 119". In the office action dated 12/12/2008, this section under this form had been checked to indicate that some, but not all, of the certified copies of the priority documents had been received. The examiner would like to clarify that all of the priority documents have been received, and this is reflected on the form PTOL-326 submitted with this office action.
2. In the office action dated 12/12/2008, claims 1-32 had been provisionally rejected for obviousness type double patenting over claims of the following copending applications: 12/088661, and 12/088647. In the reply filed on 4/13/2009, the Applicants responded to this rejection by stating that they would consider filing a terminal disclaimer in the event that the instant claims are found allowable. The rejection of these claims for obviousness type double patenting over claims of the copending

applications 12/088661 and 12/088647 was proper, and is therefore maintained. This rejection will be restated below for Applicants' convenience.

3. In the office action dated 12/12/2008, claims 1-32 had been rejected under 35 USC § 103(a) as being unpatentable over Farina et. al., WO 95/32948, in view of Pace et. al., US PG Pub. 2002/0056206. In the reply filed on 4/13/2009, the Applicants argued that Farina et. al. in view of Pace et. al. did not render the instant invention obvious, as Pace et. al. uses a different process than what is instantly claimed to form small particles in the  $\mu\text{m}$  range size. The Applicants argued that Pace et. al. teaches spray drying a molten form of a drug with a phospholipid surfactant to create the small particle size, while the instant invention claims a process comprising wet milling a dispersion of talnetant with an ionic surfactant, followed by spray drying the dispersion. This argument has been fully considered, and is not found to be persuasive. It is acknowledged that Farina et. al. teaches talnetant as a drug for therapeutic benefit, while Pace et. al. teaches the process of forming active drug microparticles by a heated suspension of a drug within an aqueous carrier with atleast one ionic surfactant, which is spray dried (Abstract, p. 9, paragraph [0089]). Pace et. al. also teaches that, in addition to phospholipids, other ionic surfactants, such as sodium lauryl sulfate, can be used (p. 12, column 1, lines 1-4), and that the particles formed have an average size in the range from 0.1 to 2  $\mu\text{m}$  (claim 13). Pace et. al. also describes a process of wet milling the drug in an aqueous medium (p. 12, paragraph [0127]; p. 24, claim 1; p. 16, paragraph [0165]), and that the active ingredient is present in the composition from 1 to 90 % (p. 19, column 2, paragraph [0199]). It is also taught that the surfactant

concentration is from 0.5 to 50 % (p. 19, paragraph [0195]), and that the carriers include mannitol and lactose (p. 26, claim 39). Additionally, it is noted that instant claims 19-32 are product-by-process claims. It is known that while product-by-process claims are limited by and defined by the stated process, the patentability of the product does not depend on the process. "If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process", *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) MPEP 2113. Therefore, as Farina et. al. teaches talnetant, and Pace et. al. teaches that a poorly soluble drug can be prepared in the 0.1 to 2.0  $\mu\text{m}$  range size by forming an aqueous dispersion of the drug with an ionic surfactant, followed by wet milling and spray drying to form the dried small particles of the drug, it would have been obvious for one of ordinary skill in the art, to use the process taught by Pace et. al. for talnetant, to form particles in the 0.1 to 2  $\mu\text{m}$  range, to increase solubility of the drug. As claims 19-32 are drawn to a product of talnetant, the patentability of these claims is considered regarding whether the product is obvious over the prior art, and not the process by which the product is prepared. Pace et. al. teaches a process of increasing the solubility of a poorly soluble drug, and Farina et. al. teaches the composition comprised of talnetant. As talnetant is a poorly soluble drug, it would have been prima facie obvious for one of ordinary skill in the art, at the time of the invention, to combine the teachings of Pace et. al. with Farina et. al. to arrive at the instant invention of a product and process comprising talnetant particles having a size range from 0.1 to 2.0  $\mu\text{m}$ . Therefore, the rejection of claims 19-32 under 35 USC §

103(a) over Farina et. al. in view of Pace et. al. was proper, and is maintained. In consideration of claims 1-18, which are directed to a process of preparing spray dried composition of talnetant particles having a size range of 0.1 to 2.0  $\mu\text{m}$ , the rejection of these claims under 35 USC § 103(a) over Farina et. al. in view of Pace et. al. is also found proper, and is maintained. The Applicants have argued that Pace et. al. teaches a process in which a molten dispersion of the drug is used to prepare the small particle size, but that the instant invention does not use a molten form of talnetant. However, it is noted that instant claim 1 cites "A process for the preparation of a spray-dried composition, the composition *comprising*". The term comprising is not exclusive, and as such the instant claim does not exclude a molten form of talnetant from being used in the process. Claims 2-18, which are dependent claims of claim 1, are interpreted in the same manner. Additionally, a new art rejection of these claims is applied, which will be explained in detail further in the office action. The rejection of claims 1-32 will also be restated for Applicants' convenience.

A new art rejection has been made in this office action. Accordingly, this action is made **NON-FINAL**.

4. Claims 1-32 are pending.
5. Claims 1-32 were examined.
6. Claims 1-32 are rejected.

***Claim Rejections-35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

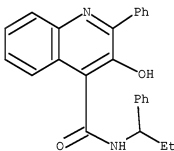
9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-32 rejected under 35 U.S.C. 103(a) as being unpatentable over Farina et. al., US 5,811,553 patent, in view of Cooper et. al., US 6,908,626 patent.

11. Instant claims 1-18 are drawn to a process of preparing talnetant particles having a  $D_v^{90}$  in the range from 0.1 to 2.0  $\mu\text{m}$ , which comprises wet milling a dispersion of the

talnetant particles with at least one ionic surfactant in a carrier, and spray drying the dispersion. The instant claims also include sodium lauryl sulfate as an ionic surfactant, and the carrier for the dispersion includes a soluble sugar, such as mannitol, and further comprises anti-agglomeration agents.

Farina et. al. teaches that talnetant (shown below) is a NK<sub>3</sub> receptor antagonist used to treat pulmonary, CNS, and neurodegenerative disorders (Abstract, column 61, Table 3, Ex. 79). However, Farina et. al. does not teach the 0.1 to 2.0  $\mu\text{m}$  particle size of the drug, or that the drug is prepared by wet milling, with ionic surfactants such as sodium lauryl sulfate, or anti-agglomeration agents.



Cooper et. al. teaches a process in which poorly soluble drugs can have improved bioavailability by creating particles of the drug which have an effective average particle size ranging from 900 nm to less than 50 nm, which is equivalent to 0.9 to 0.05  $\mu\text{m}$  (Abstract, column 6, line 65-column 7, line 8; claim 2). Cooper et. al. defines the term "effective average particle size" as that atleast 50% of the active agents have a particle size less than 100 nm, or more preferably, atleast 90% of the particles have an average particle size of less than the effective average (column 15, lines 17-28). Cooper et. al. teaches a process in which an aqueous-based dispersion is formed which also contains



a surfactant. Milling of the dispersion is followed by spray drying to create the dry particles (column 17, lines 9-37; column 18, lines 20-33; column 19, lines 3-24). Cooper et. al. also teaches sodium lauryl sulfate as a surfactant (column 12, lines 12-13), and soluble sugar carriers such as mannitol (column 15, line 64). Anti-agglomeration agents are also included (column 17, lines 7-10). It is also taught that the active drug can comprise from 0.001% to 99.5% of the composition, and the surfactants from 0.5 % to 99.9% (claims 6-9).

While Cooper et. al. does not explicitly state the amounts of surfactant and active agents present specifically regarding before or after spray drying, or that the dispersion contains 0.001 to 0.1 moles of ionic surfactant per mole of talnetant, it is taught that the amount of active drug in the formulation varies from 0.001 to 99.5%, and the amount of surfactant from 0.5 to 99.9 % (claims 6-9). Therefore, the ranges of active drug and surfactant present in the formulation taught by Cooper et. al. overlap with the ranges of talnetant and surfactant instantly claimed. While the specific amount of soluble carrier present is not explicitly taught, one of ordinary skill in the art would have expected this range to be from 10 to 75 % as instantly claimed, depending on the amount of active agent, surfactants, and other excipients present. While the specific amount of anti-agglomeration agent that is present is not explicitly taught, one of ordinary skill in the art would also expect this range to vary depending on the amount of talnetant, surfactants, and other components present, and to be within 0.1 to 10% by weight of the dispersion, and within 2 to 10% by weight of talnetant, as instantly claimed.

Farina et. al. teaches talnetant as a  $NK_3$  receptor antagonist drug which is useful for treating a variety of disorders. It is known that talnetant is a poorly soluble drug, which limits therapeutic benefit. Cooper et. al. teaches a process in which poorly soluble drugs can have improved bioavailability by preparing a decreased particle size ranging from 900 to 50 nm., or 0.9 to 0.05  $\mu\text{m}$ . Cooper et. al. also teaches that the process comprises making a dispersion of the poorly soluble drug with a preferred surfactant such as sodium lauryl sulfate, in a sugar carrier such as mannitol, followed by spray drying to form the dry particles. It would have been prima facie obvious for one of ordinary skill in the art at the time of the invention to apply the process taught by Cooper et. al. to prepare a more readily bioavailable form of talnetant, because talnetant is a poorly soluble drug, and Cooper et. al. teaches a process in which the physiological absorption of poorly soluble drugs can be improved. Therefore, a reasonable expectation of success would have been expected by applying the techniques taught by Cooper et. al. towards talnetant, and the instant invention is rendered obvious over Farina et. al., in view of Cooper et. al.

Instant claims 19-32 are product-by-process claims which are directed to a composition comprised of talnetant particles having a  $D_v^{90}$  from 0.1 to 2.0  $\mu\text{m}$ , with an ionic surfactant such as sodium lauryl sulfate, and a soluble sugar carrier such as mannitol. The amounts of talnetant, surfactant, and anti-agglomeration components present are identical to what is claimed for the process claims. As the process claims 1-18 are obvious over Farina et. al., in view of Cooper et. al., the product and composition

derived from the process are also obvious. Therefore, instant claims 19-32 are also found to be obvious over these references.

***Claim Rejections-35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farina et. al., US 5,811,553 patent, in view of Pace et. al., US PG Pub 2002/0056206.

16. The instant claims are drawn to a product and a process of preparing talnetant particles having a  $D_v^{90}$  in the range from 0.1 to 2.0  $\mu\text{m}$ , which comprises wet milling a dispersion of the talnetant particles with at least one ionic surfactant in a carrier, and spray drying the dispersion. The instant claims also include sodium lauryl sulfate as an ionic surfactant, and the carrier for the dispersion includes a soluble sugar, such as mannitol, and further comprises anti-agglomeration agents.

Farina et. al. teaches that talnetant is useful as an  $\text{NK}_3$  receptor antagonist for treating pulmonary, CNS, and neurodegenerative disorders (Abstract; pg. 1, line35-pg. 2, line 24; column 61, Table 3, Ex. 79).

Farina et. al. does not teach the process of preparing talnetant with bulking agents or surfactants and sugar carriers. Pace et. al. teaches a process of preparing a composition in which the active drug is present in a small particle size by milling of the composition in an aqueous based medium (column 12, paragraph [0127]; p. 24, claim 1; p. 16, paragraph [0165]), followed by spray drying (Abstract). Pace et. al. teaches ionic surfactants (p. 12, column 1, lines 1-4), as well as a soluble carrier (p. 26, claim 39), and particle sizes within the range of 0.1 to 2.0  $\mu\text{m}$  (claims 11-13). Pace et. al. also teaches formation of dispersion (p. 16, paragraph [0167]), and that the active ingredient is present from 1 to 90 % (p. 19, column 2, paragraph [0199]), which includes the ranges as stated for instant claims 3 and 4. Sodium lauryl sulfate is also taught as a surfactant (p. 12, column 1, lines 1-4), and it is also taught that the amount of surfactant

present is within 0.5 to 50 % (p. 19, paragraph [0195]), which meets claims 8 and 23. Although Pace et. al. does not specifically teach concentrations such as 0.05% or 0.001 to 0.1 moles of ionic surfactant to talnetant, it is considered routine optimization to establish working ranges within the art. Pace et. al. also teaches a sugar carrier such as mannitol and lactose (p. 26, claim 39), as claimed in instant claims 11-13, and 24-26. It is also taught that the concentration of the carrier ranges from 0.1 to 90% (pg. 19, paragraph [0199]), which is within the range taught by instant claims 14 and 15. Pace et. al. also teaches that anti-agglomeration agents are present from 0.1 to 20% (p. 22, paragraph [0229]), which meets claims 16-18, and 28-29.

Claims 19-32 are product-by-process claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process", *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) MPEP 2113. The process of manufacture as cited in instant claim 1 is known to those of ordinary skill in the art, and the composition as disclosed from the process is not novel and non-obvious over the prior art.

It would have been *prima facie* obvious to one of ordinary skill in the art, at the time of the invention, to modify the method of preparing the composition of talnetant, as taught by Farina et. al. by applying the teachings of Pace et. al. to arrive at a microparticle sized composition of talnetant. Talnetant is a poorly soluble drug, and

Pace et. al. teaches a process in which poorly soluble drugs are prepared to for increased absorption. Therefore, one of ordinary skill in the art would have been motivated to use the method as taught by Pace et. al. to prepare a process and composition of talnetant, in which the bioavailability of talnetant is increased. The instant invention is made obvious over Farina et. al., in view of Pace et. al.

### ***Claim Rejections-Obviousness-Type Double Patenting***

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 12/088661. Although the conflicting claims are not identical,

they are not patentably distinct from each other because claims 1-22 of the copending application embrace the same invention as directed by instant claims 1-32.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Instant claims 1-32 are drawn to product claims comprising microparticle sized talnetant and a process of preparing a microparticle sized composition of talnetant, which contains ionic surfactants and sugar carriers. Claims 1-22 in the copending application are also drawn to a process of preparing and a composition comprised of talnetant, ionic surfactants, and sugar carriers. The claims of the copending application also include the excipient povidone; however, adding different surfactants or carrier agents to a composition is considered part of routine optimization of working ranges, and would have been obvious for one of ordinary skill in the art.

20. Claims 1-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 12/088647. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the copending claims embrace the same invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

21. Instant claims 1-32 are drawn to product claims comprising microparticle sized talnetant and a process of preparing a microparticle sized composition of talnetant, which contains ionic surfactants and sugar carriers. Claims 1-29 of the copending

application 12/088647 are drawn to a composition comprised of talnetant and a process of preparing microparticle sized talnetant which includes ionic surfactants and sugar carriers. The copending application also includes excipients such as povidone and erythritol; however, adding different surfactants or carrier agents to a composition is considered part of routine optimization of working ranges, and would have been obvious for one of ordinary skill in the art.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 8:00 AM - 6:30 PM EST, with Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.P.  
/SREENI PADMANABHAN/  
Supervisory Patent Examiner, Art Unit 1617